

in the public press and in medical journals.

(b) Labeling these products with a warning that they are not for oral ingestion has not been effective in protecting the public. Misuse of stramonium preparations can cause serious toxic effects including toxic delirium, visual disturbances, fever, and coma. A number of serious reactions have already occurred from the oral ingestion of such products.

(c) On the basis of this information, the Commissioner of Food and Drugs has concluded that such articles have a potentiality for harmful effect through misuse and are not safe for use except under the supervision of a physician. In the interest of public health protection, therefore, the Food and Drug Administration adopts the following policy:

(1) Preparations containing stramonium supplied from the leaves, seeds, or any other part of the plant in the form of a powder, pipe mixture, cigarette, or any other form, with or without admixture of other ingredients, will be regarded as misbranded if they are labeled with directions for use in self-medication.

(2) The Food and Drug Administration will, on request, furnish comment on proposed labeling limiting any such preparation to prescription sale.

(d) The labeling or dispensing of stramonium preparations contrary to this statement after 60 days following the date of its publication in the FEDERAL REGISTER may be made the subject of regulatory proceedings.

Subpart B—New Drug or Prescription Status of Specific Drugs

§ 250.100 Amyl nitrite inhalant as a prescription drug for human use.

(a) Amyl nitrite inhalant has been available over-the-counter for emergency use by the patient in the management of angina pectoris for a number of years. As a result of a proposed policy statement published August 25, 1967 (32 FR 12404), the Commissioner of Food and Drugs received reports of the abuse of this drug by those who do not require it for medical purposes. Additionally, comment included a great deal of concern expressed by individual

physicians, medical associations, pharmaceutical associations, manufacturers, and State and local health authorities. Based on the information available, it is the opinion of the Commissioner of Food and Drugs, concurred in by the Food and Drug Administration Medical Advisory Board, that amyl nitrite inhalant is a drug with a potentiality for harmful effect and that it should be removed from over-the-counter status and restricted to sale on the prescription of a practitioner licensed by law to administer such drug.

(b) Therefore, amyl nitrite inhalant will be regarded as misbranded unless the labeling on or within the package from which the drug is to be dispensed bears adequate information for its safe and effective use by physicians, in accordance with § 201.100(c) of this chapter, and its label bears the statement "Rx only."

(c) Regulatory proceedings may be initiated with regard to the interstate shipment of amyl nitrite inhalant that is labeled, advertised, or dispensed contrary to this statement of policy if such act occurs after July 1, 1969.

[40 FR 14033, Mar. 27, 1975, as amended at 67 FR 4906, Feb. 1, 2002]

§ 250.101 Amphetamine and methamphetamine inhalers regarded as prescription drugs.

(a) Recurring reports of abuse and misuse of methamphetamine (also known as desoxyephedrine) inhalers show that they have a potentiality for harmful effect and that they should not be freely available to the public through over-the-counter sale. From complaints by law-enforcement officials, health officials, individual physicians, parents, and others as well as from Food and Drug Administration investigations, it is evident that the wicks from these inhalers are being removed and the methamphetamine they contain is being used as a substitute for amphetamine tablets. Amphetamine tablets and amphetamine inhalers have been restricted to prescription sale because of their potentiality for harm to the user.

(b) It is the considered opinion of the Food and Drug Administration that, in order to adequately protect the public

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health, inhalers containing methamphetamine or methamphetamine salts (d-desoxyephedrine, or dl-desoxyephedrine, or their salts), as well as amphetamine inhalers should be restricted to prescription sale and should be labeled with the statement “Rx only.”

[40 FR 14033, Mar. 27, 1975, as amended at 67 FR 4906, Feb. 1, 2002]

§ 250.102 Drug preparations intended for human use containing certain “coronary vasodilators”.

(a)(1) The Food and Drug Administration finds that the following “coronary vasodilators” are extensively regarded by physicians as safe and useful as employed under medical supervision for the management of angina pectoris in some patients:

Amyl nitrite.
Erythryl tetranitrate.
Mannitol hexanitrate.
Nitroglycerin.
Potassium nitrite.
Sodium nitrite.

(2) Additionally, new-drug applications have been approved for products containing:

Inositol hexanitrate.
Isosorbide dinitrate.
Octyl nitrite.
Pentaerythritol tetranitrate.
Triethanolamine trinitrate biphosphate (trolnitrate phosphate).

(b) The Food and Drug Administration also finds that there is neither substantial evidence of effectiveness nor a general recognition by qualified experts that such drugs are effective for any of the other purposes for which some such drugs are promoted to the medical profession in labeling and advertising. In particular, neither clinical investigations nor clinical experience justify any representations that such drugs are effective in the management of hypertension; in the management of coronary insufficiency or coronary artery disease, except for their anginal manifestations; or in the management of the post coronary state, except angina pectoris present after coronary occlusion and myocardial infarction.

(c) Any preparation containing such drugs that is labeled or advertised for

any use other than management of angina pectoris, or that is represented to be efficacious for any other purpose by reason of its containing such drug, will be regarded by the Food and Drug Administration as misbranded and subject to regulatory proceedings, unless such recommendations are covered by the approval of a new-drug application based on a showing of safety and effectiveness.

(d) Any such drug in long-acting dosage form is regarded as a new drug that requires an approved new-drug application before marketing.

(e) Any of the drugs listed in paragraph (a)(2) of this section is regarded as a new drug that requires an approved new-drug application. Articles for which new-drug approvals are now in effect should be covered by supplemental new-drug applications as necessary to provide for labeling revisions consistent with this policy statement.

§§ 250.103–250.104 [Reserved]

§ 250.105 Gelsemium-containing preparations regarded as prescription drugs.

It is the consensus of informed medical opinion that the margin of safety between the therapeutic and toxic concentration of gelsemium is narrow and it is difficult to predict the point at which the dose will be toxic. Very small doses may cause toxic symptoms. It is therefore the view of the Food and Drug Administration that gelsemium is not a proper ingredient in any product that is to be sold without prescription. Accordingly, any drug containing gelsemium will be regarded as misbranded under section 503(b)(4) of the Federal Food, Drug, and Cosmetic Act if its label fails to bear in a prominent and conspicuous fashion the statement “Rx only.”

[40 FR 14033, Mar. 27, 1975, as amended at 67 FR 4906, Feb. 1, 2002]

§§ 250.106–250.107 [Reserved]

§ 250.108 Potassium permanganate preparations as prescription drugs.

(a) There have been a number of reports in the medical literature of serious injuries to women resulting from the misuse of potassium permanganate